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MRJ

Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MD394N

Food and Drug Administration
555 Winderley Place
Suite 200
Orlando, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-34

February 12, 1999

Raymond L. Schilson, President
A to Z Sandwich Company
531 Osceola Street
Jacksonville FL 32204

Dear Mr. Schilson:

On October 16, 19 and 22, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 531 Osceola Street, Jacksonville, Florida. The investigator documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the tuna salad sandwiches processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (The Act), as follows:

> Failure to list the food safety hazard of pathogen growth in your HAACP plan for tuna salad sandwiches. [21 CFR 123.6(c)]

In addition, you have failed to establish adequate verification procedures in your HACCP plan for tuna salad sandwiches, i.e., the plan only identifies the individual responsible for verification and does not include a description of the verification procedure or frequency of verification. [21 CFR 123.6(c)(6)]

Your corrective action plan for food additives at the receiving critical control point is inadequate. There are no provisions in the corrective action portion of your HACCP plan to ensure that the cause of the deviation is corrected or responsibility is assigned for taking the step.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory enforcement action without further notice. These actions may include, but are not limited to, seizure and injunction. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,

Douglas D. Tolen
Director
Florida District